K023213

ANODIA SYSTEMS

Dr. Thad Overmyer
514 South Third Street
Danville, Ky 40422
Phone: 1-866-246-2548
Fax: 1-866-926-8246

510 (k) Summary

Anodia Systems
Dr. Thad Overmyer
General Manager/Owner
514 South Third Street
Danville, Kentucky 40422
TEL: 859-236-4778
FAX: 859-236-9136
Dr. Thad Overmyer
September 18, 2002

JAN 16 2003

Device:

- Trade Name—RDH-2000
- Common Name—Bottle System
- Classification—Dental operative unit and accessories (per 21CFR section 872.6640)

Legally Market Devices of Equivalence

- K882491, Cutting Fluid System for Dental High Speed Drills, Steri-Sol Inc.
- K962665, A-Dec Self-Contained Water System A-Dec, Inc.

Description: The RDH-2000 is a portable bottle system. It dispenses solution from its bottle to a scalar. It is attached to the dental unit's quick disconnect air to pressurize the system.

The RDH-2000 is composed of two parts; the manifold and the bottle. The manifold has a male quick disconnect. The quick disconnect connects to the dental units air supply via a female air quick disconnect. The system becomes pressurize only when attached to the dental unit. Within the manifold after the male quick disconnect is an internal preset mini air regulator. This is preset at 35 psi. The pressurized air is vented into the bottle via the top of the manifold. On the side of the manifold is a pressure relief button to allow the bottle to be depressurized before unscrewing. The threads in the manifold accept the 28 mm threads of the bottle. A pick up tube goes to the base of the bottle which allows a means for the solution to exit. The pick up tube goes into the manifold and connects to a female quick disconnect with automatic shut-off. The female quick disconnect with the automatic shut-off prevents solution from being dispensed when the system is pressurized. A scalar with a male quick disconnect can attach at this point. This allows the scalar to obtain solution from the bottle.

The bottle is a one liter high density polyethylene bottle. The threads have vertical grooves which acts as a pressure relief valve.

Intended Use: The RDH-2000 is designed for the use of furnishing a solution to a scalar which does not have a reservoir for solutions. The RDH-2000 connects to air quick disconnect of the dental unit to pressurize the RDH-2000. The quick disconnect makes the system portable and convenient to store when not in use.

Technological Characteristics: The RDH-2000 has a high density polyethylene bottle (reservoir) as the Adec Self-Contained Water System (K 962665). The bottles in both have vertical grooves to act as a pressure relief valve. The manifolds of Adec and RDH-2000 are constructed from delrin material. The Adec Self-Contained Water System, Cutting Fluid System (K882491), and the RDH-2000 have pressure regulators. These devices are pressurized by air to dispense a solution.

The RDH-2000 has the following enhancements: 1) pressure relief valve to allow release of pressure from bottle before unscrewing the bottle; 2. preset pressure regulator valve built into the manifold to prevent tampering; 3. male quick disconnect for attachment to dental unit allowing RDH-2000 to be removed and stored when not in use; and 4. female quick disconnect with automatic shut off preventing solution from being dispensed freely from reservoir when RDH-2000 is pressurized.

Results of in-house testing indicated that the RDH-2000 performed to dispense a solution when air activated as designed.

I believe that the design of the RDH-2000 with the enhancements creates a safe and effective system for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Thad Overmyer
Anodia Systems
514 South Third Street
Danville, Kentucky 40422

JAN 16 2003

Re: K023213
Trade/Device Name: RDH-2000/C-1310
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: December 30, 2002
Received: January 3, 2003

Dear Dr. Overmyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023213

Device Name: RDH-2000/C-1310

Indications For Use:

Portable pressurized system to deliver a solution to a scalar. Scalar being a dental device powered by air or electricity to remove tartar from the teeth requiring a solution for its performance.

(PLEASE DO NOT WIRTE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109

(Optional Format 1-2-9)

Susan Runne

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023213